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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,934	10/27/2003	Jacob Richter	2388/46607	2137

23838 7590 03/24/2008

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT	**PAPER NUMBER**
3773	

MAIL DATE	DELIVERY MODE
03/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,934	RICHTER ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32 and 34-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32 and 34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to Applicant's amendment received on 17 December 2007.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 32, 34-36, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. (3,788,327) in view of Rubinstein (5,433,701), and further in view of Goldsmith (5,053,040).

Donowitz discloses a method (see entire document) comprising the step of providing an intraocular implant (for example, see Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Donowitz fails to specifically disclose inserting the implant through scleral tissue. However, Donowitz discloses directing the implant to an implantation site, which includes either directly through the cornea or through other areas of the eye (column 4, lines 14-17).

Rubinstein discloses a method (see entire document) comprising the step of providing an intraocular implant (for example, see Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22). Rubinstein teaches cutting a slit in a first portion of the conjunctiva of the eyeball at a distance from a second portion of the conjunctiva which normally covers an implantation site, forming a flap with the second portion of the conjunctiva that forms an opening, directing the implant through the opening in the conjunctiva, directing the implant to the implantation site, inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), and closing the second portion over the implantation site (for example, see Figure 2). Rubinstein teaches this method minimizes the possibility that the iris will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway of the implant (column 3, lines 48-68, through column 4, lines 1-7) and permits adequate healing (for example, see column 7, lines 25-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Donowitz as taught by Rubinstein in order to provide the advantages described above. Donowitz in view of Rubinstein fails to disclose a delivery device as claimed.

Goldsmith discloses a method of delivering an implant (see entire document) Goldsmith teaches the steps of attaching an implant (12) with a flange (64) to a delivery

device (10) comprising a rodlike instrument, wherein the rodlike instrument has an abutment surface (16) for abutting the flange (64) of the implant (the abutment surface has an angle generally corresponding to an angle of the flange in that both have an angle of generally zero degrees), directing the implant (12) by the delivery device (10) to an implantation site, inserting the implant (12), and withdrawing the device (for example, see Figures 6-9). Goldsmith further teaches that using the delivery device described above facilitates placement of an implant by preventing tears or excessive stretching of the incision at the implantation site (for example, see column 2, lines 16-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Goldsmith in order to be able install the implant without tearing and stretching the incision at the implantation site, resulting in satisfactory positioning of the implant (for example, see column 2, lines 4-21). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the abutment surface of Goldsmith with an angle corresponding to the angle of the flange of the Donowitz in view of Rubinstein implant, since Goldsmith teaches the abutment surface lies flush with the flange (64) of the implant (12; for example, see Figures 6-9).

4. Claims 37-43 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. in view of Rubinstein in view of Goldsmith, and further in view of Wong et al. (5,000,731).

Donowitz discloses a method (see entire document) comprising the step of

providing an intraocular implant (for example, see Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Donowitz fails to specifically disclose inserting the implant through scleral tissue. However, Donowitz discloses directing the implant to an implantation site, which includes either directly through the cornea or through other areas of the eye (column 4, lines 14-17).

Rubinstein discloses a method (see entire document) comprising the step of providing an intraocular implant (for example, see Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22). Rubinstein teaches cutting a slit in a first portion of the conjunctiva of the eyeball at a distance from a second portion of the conjunctiva which normally covers an implantation site, forming a flap with the second portion of the conjunctiva that forms an opening, directing the implant through the opening in the conjunctiva, directing the implant to the implantation site, inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), and closing the second portion over the implantation site (for example, see Figure 2). Rubinstein teaches this method minimizes the possibility that the iris will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway of the implant (column 3, lines 48-68, through column 4, lines 1-7) and permits adequate healing (for example, see column 7, lines 25-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify the method of Donowitz as taught by Rubinstein in order to provide the advantages described above. Donowitz in view of Rubinstein fails to disclose the delivery device as claimed.

Goldsmith discloses a method of delivering an implant (see entire document) Goldsmith teaches the steps of attaching an implant (12) with a flange (64) to a delivery device (10) comprising a rod-like instrument, wherein the rod-like instrument has an abutment surface (16) for abutting the flange (64) of the implant (the abutment surface has an angle generally corresponding to an angle of the flange in that both have an angle of generally zero degrees), directing the implant (12) by the delivery device (10) to an implantation site, inserting the implant (12), and withdrawing the device (for example, see Figures 6-9). Goldsmith further teaches that using the delivery device described above facilitates placement of an implant by preventing tears or excessive stretching of the incision at the implantation site (for example, see column 2, lines 16-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Goldsmith in order to be able install the implant without tearing and stretching the incision at the implantation site, resulting in satisfactory positioning of the implant (for example, see column 2, lines 4-21). Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the abutment surface of Goldsmith with an angle corresponding to the angle of the flange of the Donowitz in view of Rubinstein implant, since Goldsmith teaches the abutment surface (16) lies flush with the flange (64) of the implant (12; for example, see Figures

6-9). Donowitz in view of Rubinstein in view of Goldsmith fails to disclose the implant has a side opening, or hole, that serves as a marker that is visible upon penetration through scleral tissue.

Wong et al. disclose an implant (see entire document) providing a passage for fluid flow in order to reduce pressure within an organ. Wong et al. teach circumferential holes (13) in order to facilitate fluid drainage (for example, see column 3, lines 43-47). It is obvious that these circumferential holes (13) may be used as "markers" since they are located on the inlet end of the tube, which would be clearly visible on the implant upon penetration through the scleral tissue (see Figure 1 of Donowitz et al. for illustration). Therefore, to construct the implant of Donowitz et al. in view of Rubinstein in view of Goldsmith with markers, such as circumferential holes, as taught by Wong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate fluid drainage.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 32 and 34-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 12, 13, and 15 of U.S. Patent No. 5,702,414. The conflicting claims are not identical, but they are not patentably distinct from the reference claims because the claims of the patent "anticipate" the claims of the application.

Response to Arguments

7. Applicant's arguments filed 08 May 2007 with respect to claims 32 and 34-45 have been fully considered but they are not persuasive. Applicant generally argues that the references do not disclose or suggest each and every element claimed. Examiner respectfully disagrees and refers the applicant to the new rejection above for further details.

Applicant further argues that there is no reason that a person of ordinary skill would look to the non-analogous Goldsmith myringotomy device and method for modification of Donowitz and/or Rubinstein. However, the Goldsmith reference was simply used to show that delivery devices, such as that claimed, are well known. Goldsmith teaches a delivery device for delivering an implant having a flange, a tube passage, an inlet end, and an outlet end. It is well within the general knowledge of one having ordinary skill in the art to apply a known technique to a known device to yield predictable results. Therefore, it would have been obvious to one having ordinary skill in

the art at the time the invention was made to utilize the delivery device taught by Goldsmith in the method of Donowitz in view of Rubinstein. Doing so would provide an easy and effective way of delivering the implant to the implantation site (see rejection above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 9-5:30 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
March 12, 2008

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773